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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,917	10/28/2003	Edmond Differding	2003_1548	3995

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EXAMINER

SHIAO, REI TSANG

ART UNIT PAPER NUMBER

1626

DATE MAILED: 09/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/693,917

Applicant(s)

DIFFERDING ET AL.

Examiner

Robert Shiao

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on application filed on 10/28/2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 10/204,266.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/23/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. This application claims benefit of the foreign application:

UNITED KINGTON 0004297.8, with a filing date 02/23/2000.

2. Claims 1-5 are pending in the application.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. It is noted that the claims contains subject matter "and other neurological disorders", "trigeminal and other neuralgia", "other movement disorders", and "and other degenerative diseases", which were not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention, i.e., see claim 3, lines 2-6.

4. Claims 3-4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of use treating bipolar disorders, does

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not reasonably provide enablement for a method of use treating schizophrenia. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1988):

- 1) Nature of invention.
- 2) State of prior art.
- 3) Level of ordinary skill in the art.
- 4) Level of predictability in the art.
- 5) Amount of direction and guidance provided by the inventor.
- 6) Existence of working examples.
- 7) Breadth of claims.
- 8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See below:

1) Nature of the invention.

The claim is drawn to "a method of use treating other neurological disorders, trigeminal and other neuralgia, other movement disorders, and other degenerative diseases without limitation", see claim 1, lines 2-6.

2) State of the prior art.

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The reference Honore et al. GB 1309692 does not indicate which compounds of instant organic carbonate scavenger may be useful in the claimed invention. Honore et al. '692 is pertaining to a pyrrolidine compound for treatment of epilepsy.

3) Level of ordinary skill in the art.

The level of ordinary skill in the art is high. The claims are drawn to "a method of use treating other neurological disorders, trigeminal and other neuralgia, other movement disorders, and other degenerative diseases without limitation". Applicant's specification does not enable the public to prepare such "a method of use treating other neurological disorders, trigeminal and other neuralgia, other movement disorders, and other degenerative diseases without limitation" by the instant examples disclosed in the specification.

4) Level of predictability in the art.

The claims are drawn to "a method of use treating other neurological disorders, trigeminal and other neuralgia, other movement disorders, and other degenerative diseases without limitation", see claim 1, lines 2-6. Different types of the genus of processes require various experimental procedures and without guidance that is applicable to all possible "a method of use treating other neurological disorders, trigeminal and other neuralgia, other movement disorders, and other degenerative diseases without limitation", there would be little predictability in the scope of claimed methods.

5) Amount of direction and guidance provided by the inventor.

The claims are drawn to “a method of use treating other neurological disorders, trigeminal and other neuralgia, other movement disorders, and other degenerative diseases without limitation”, encompasses a vast number of methods. Applicant’s limited guidance does not enable the public to prepare such “a method of use treating other neurological disorders, trigeminal and other neuralgia, other movement disorders, and other degenerative diseases without limitation” in the specification. There is no enablement for “a method of use treating other neurological disorders, trigeminal and other neuralgia, other movement disorders, and other degenerative diseases without limitation”, which are neither enabled nor supported in the specification. There is no enablement for “a method of use treating other neurological disorders, trigeminal and other neuralgia, other movement disorders, and other degenerative diseases without limitation”, i.e., treating schizophrenia, which are neither enabled nor supported in the specification.

6) Existence of working examples.

The claims are drawn to “a method of use treating other neurological disorders, trigeminal and other neuralgia, other movement disorders, and other degenerative diseases without limitation”, encompasses a vast number of methods. Applicant’s limited working examples do not enable the public to prepare such a numerous amount of “a method of use treating other neurological disorders, trigeminal and other neuralgia, other movement disorders, and other degenerative diseases without limitation” in the specification. Applicants claim “a method of use treating other neurological disorders, trigeminal and other neuralgia, other movement disorders, and

other degenerative diseases without limitation", however, the specification provides only limited examples of the methods.

7) Breadth of claims.

The claims are extremely broad due to the vast number of possible "a method of use treating other neurological disorders, trigeminal and other neuralgia, other movement disorders, and other degenerative diseases without limitation".

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The specification did not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with this claim. In particular, the specification failed to enable the skilled artisan to practice the invention without undue experimentation. The skilled artisan would have a numerous methods in order to obtain "a method of use treating other neurological disorders, trigeminal and other neuralgia, other movement disorders, and other degenerative diseases without limitation" as claimed. Based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could not perform the claimed compounds without undue experimentation, see *In re Armbruster* 185 USPQ 152 CCPA 1975. Deletion of the limitation "and other neurological disorders", "trigeminal and other neuralgia", "other movement disorders", and "and other degenerative diseases", would obviate the rejection, see page 23-24.

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5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3, line 2, is indefinite because it is recited as a method claim and use the term "including" which is open-ended. A method claim cannot use open-ended language when defining the parameters of the method. By deleting "including" would obviate the rejection.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

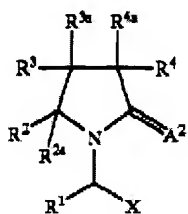
patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-5 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 21, and 23 of Differding et al. US 6,784,197. Although the conflicting claims are not identical, they are not patentably distinct from each other. The reasons are given, *infra*.

Applicants claim (4R) and (4S) diastereoisomers of (2S)-2-[2-oxy-4-propylpycolidiny]butanamide or a pharmaceutically acceptable salt thereof and its method of use treating epilepsy, and the compounds are found in the pages 1-11 of the specification.

Differding et al. claim a 2-oxo-pyrrolidine compound of formula (I) or a pharmaceutically acceptable salt thereof,



, as agents treating epilepsy, wherein the variable

R¹ represent alkyl; the variable X represents -CA¹NR⁵R⁶; the variable A represents oxygen, and variables R⁵ and R⁶ independently represents hydrogen. Differding et al.

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claim two compounds (2S)-2-[(4S)-2-oxo-4-propylpyrrolidinyl]butanamide and (2S)-2-[(4R)-oxo-4-propylpyrrolidinyl]butanamide, which clearly anticipate the instant claimed compounds, see column 96, lines 54-55 (i.e. claim 21).

The difference between the instant claims and Differding et al. is that the instant claimed compounds are diastereoisomers of Differding et al. compounds of formula (I). However, the compounds of Differding et al. (i.e., claims 21 and 23) read on the instant compounds and methods of use.

One having ordinary skill in the art would find the instant claims *prima facie* obvious **because** one would be motivated to employ the compounds/diastereoisomers of Differding et al. to obtain instant diastereoisomers compounds of claim 1 and their methods of use.

The motivation to make the claimed compounds derives from the expectation that the instant claimed diastereoisomers compounds derived from known Differding et al. compounds and would possess similar activity (i.e., agents for treating epilepsy) to that which is claimed in the reference.

Telephone Inquiry

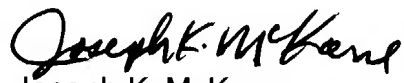
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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Robert Shiao, Ph.D.
Patent Examiner
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September 1, 2004